

# The Restorative Effects of Three Commonly Used Materials on Hearing Thresholds in Patients with Austin-Kartush Type A Ossicular Defects

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## ABSTRACT

**Objective:** This study aims to compare the effect on the hearing results of three different materials used in ossiculoplasty for patients with chronic otitis media (COM) and Austin-Kartush type A defect.

**Materials and Methods:** This retrospective study includes 79 patients with the Austin-Kartush type A defect due to COM. The ossiculoplasty had been performed with a glass ionomer cement (GIC), titanium partial ossicular replacement prosthesis (PORP), or incus interposition between 2011-2021. Age, gender, operation side, hearing thresholds, computed tomography images, intraoperative findings, and middle ear risk index (MERI) were obtained from medical records. Air-conduction (AC) and bone-conduction (BC) thresholds were calculated by averaging the threshold values for 500, 1,000, 2,000 and 3,000 Hz, and air-bone gap (ABG) values were calculated by subtracting the BC thresholds from the AC thresholds, preoperatively and postoperatively. Hearing gains were obtained by subtracting ABG values in the first postoperative year from the preoperative ABG values.

**Results:** This study included 32 male and 47 female patients. The GIC group had 28 patients, the incus interposition group had 28, and the PORP group had 23. No statistically significant difference occurred among the groups regarding MERI scores ( $p = 0.699$ ). The mean preoperative ABG levels were  $37.46 \pm 9.23$  dB in the GIC group,  $38.96 \pm 11.35$  dB in the incus interposition group, and  $37.34 \pm 10.16$  dB in the PORP group, while the mean postoperative ABG levels were  $24.42 \pm 11.20$  dB in the GIC group,  $23.25 \pm 10.09$  dB in the incus interposition group, and  $22.82 \pm 13.59$  dB in the PORP group ( $p = 0.814$ ). The ABG gains were  $13.75 \pm 11.66$  dB in the GIC group,  $15.71 \pm 11.55$  dB in the incus interposition group, and  $14.52 \pm 9.98$  dB in the PORP group ( $p = 0.803$ ).

**Conclusion:** The incus long process defect or lack of the incus due to COM may be repaired with GIC, incus interposition, or titanium PORP, all with similar ABG gains.

**Keywords:** Chronic otitis media, ossiculoplasty, Austin-Kartush type A defect, glass ionomer cement, incus interposition, partial ossicular replacement prosthesis

## INTRODUCTION

The ossicular chain is located in the middle ear and transmits sound energy from the tympanic membrane to the oval window. Chronic otitis media (COM) can cause ossicular chain defects that are commonly seen in the incus long process (1). Various prostheses and materials have been developed for restoring ossicular defects, and the characteristics of successful ossiculoplasty methods include low extrusion rates, biocompatibility, cost-effectiveness, no transmission

of contagious diseases, long-term stability, and the effective biomechanical transmission of sound. Ossiculoplasty in the absence of incus or incus long process defects can be performed with an incus remnant, bone, cartilage, glass ionomer cement (GIC), or partial ossicular replacement prosthesis (PORP) (2-3).

The aim of this study is to compare effects on the hearing results of three different materials (GIC, incus remnant, and PORP) used for ossicular reconstruction in patients with COM-based Austin-Kartush type A ossicular defects.

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## MATERIALS AND METHODS

This study was approved by ethics review board of our tertiary hospital (Date: May 11, 2022, No: 2022/313). A total of 106 consecutive patients with defect of the incus or incus long process (Austin-Kartush type A) because of COM were reviewed retrospectively. These patients had each undergone an operation using the canal wall up mastoidectomy between 2011-2021. The exclusion criteria of this study were the presence of tympanosclerosis (13 patients), a graft failure (2 patients), PORP extrusion (2 patients), fixation of the malleus or the stapes (3 patients), and prior history of otologic interventions (7 patients). This study examined the remaining 79 patients. Inclusion criteria were comprised of patients having small retraction pockets, cholesteatomas limited to the mesotympanum and not reaching beyond the antrum, tympanic membrane perforation, and conductive or mixed type hearing loss.

The study obtained information about age, gender, operation side, hearing thresholds, computed tomography images, intraoperative findings, and middle ear risk index (MERI) from the patients' medical records.

### Audiological Evaluation

Postoperative audiometric evaluations were performed in the third, sixth, and twelfth months after surgery. Air-conduction (AC) and bone-conduction (BC) thresholds were calculated by averaging at the threshold values for the frequencies of 500, 1000, 2000, and 3,000 Hz, with the air-bone gap (ABG) values being calculated by subtracting the BC thresholds from the AC thresholds, preoperatively and postoperatively (4). Hearing gains were obtained by subtracting the ABG values in the first postoperative year from the preoperative ABG values.

Preoperative and postoperative ABG scores were categorized as grade I (0-10 dB), grade II (11-20 dB), grade III (21-30 dB), and grade IV (> 30 dB) (4). Postoperatively, ABG scores of 20 dB or less were regarded as a successful ossiculoplasty.

### Surgical Procedures and Groups

All surgeries were performed using an operating microscope under general anesthesia. The edges of the tympanic membrane perforation were refreshed and the tympanomeatal flap was elevated. Retraction pockets with or without cholesteatoma were removed, if present. The middle ear and ossicular chain were observed under the microscope. Upon detecting the incus or its long process defect, the mobility of the malleus and stapes was checked gently by tapping.

In the presence of a useless incus destroyed by cholesteatoma or surrounded by cholesteatoma, the incudomalleolar joint was disarticulated and the incus was removed from the middle ear. If a useful incus was present, it was used for restoring the ossicular integrity based on the size of the defect in the incus long process. The autograft incus was used for ossicular reconstruction when present and useful.

For an incus long process defect smaller than one-third the length of the incus long process, ossicular reconstruction was

performed by re-bridging, using a piece of GIC (AquaCem, Dentsply, Konstanz, Germany). The mucosa covering the incus long process remnant and stapes capitulum was first peeled back. After preparing a dry medium around the ossicles, a piece of GIC was placed between the stapes capitulum and the incus long process remnant (GIC group).

For a defect greater than two-thirds the length of the incus long process, the incus was removed entirely (5). The incus was reshaped with a small cutting-burr, and an acetabulum for the stapes capitulum was created. A small groove was created to fit the malleus handle. The ossicular chain continuity was maintained by interposing the sculptured incus between the stapes capitulum and the malleus handle (incus interposition group).

For the incus that was not available, largely destroyed, or surrounded by the cholesteatoma matrix, ossicular reconstruction was performed using the titanium PORP (Dmetrixcell, divine medicure technology, GJ, India; PORP group). PORP length was adjusted appropriately for the distance between the stapes capitulum and the tympanic membrane, and the PORP was placed onto the stapes capitulum. A small piece of cartilage was placed between the headplate of the titanium PORP and the tympanic membrane to prevent extrusion.

A cartilage-perichondrium composite graft from the tragus was used in all patients to repair the tympanic membrane perforation. Patients were regularly examined, and audiograms were obtained in the third, sixth, and twelfth month after operation. The graft was considered a failure if the tympanic membrane perforated within the first year after operation.

### Statistical Analysis

Statistical analysis was performed using SPSS (version 24.0; IBM, SPSS Inc.), with the data being shown as mean  $\pm$  standard deviation for continuous variables and number of cases for categorical variables. Normal distribution of the data was checked using the Shapiro-Wilk test. The  $\chi^2$  test was employed for comparing differences between groups in terms of gender. One-way analysis of variance (ANOVA) was employed to compare the mean age, preoperative ABG, preoperative MERI, postoperative change in ABG (C-ABG), and postoperative frequency-specific C-ABG values among the groups. Multivariate linear regression was performed to assess the relative effect of the independent variables (surgery type and MERI values) on the postoperative C-ABG values, with  $p$  values < 0.05 being regarded as statistically significant.

## RESULTS

This study included a total of 79 patients (32 males and 47 females). The GIC group had 28 patients, the incus interposition group had 28 patients, and the PORP group had 23 patients. There were eight males and 20 females in the GIC group, 11 males and 17 females in the incus interposition group, and 13 males and 10 females in the PORP group. The mean age of all patients was 34.75 $\pm$ 14.76 years (Range=9-68 years). Forty patients had the operation in their right ear and 39 in their

left ear. When evaluating the gender distributions among all three groups, there was no statistically significant difference ( $p=0.127$ ). The mean age was similar among all groups ( $p=0.933$ ). Table 1 shows the demographic characteristics for all the patients.

The mean MERI score for all patients was  $4.74\pm1.42$ . The mean MERI scores for each group were  $4.57\pm1.25$  for the GIC group,  $4.89\pm1.47$  for the incus interposition group, and  $4.78\pm1.59$  for the PORP group. No statistically significant difference occurred among the groups regarding MERI scores ( $p=0.699$ ).

The mean preoperative and postoperative ABG values for all patients were  $37.96\pm10.19$  dB and  $23.54\pm11.45$  dB, respectively, with a mean ABG gain of  $14.67\pm11.05$  dB. The mean preoperative ABG levels were  $37.46\pm9.23$  dB for the GIC group,  $38.96\pm11.35$  dB for the incus interposition group, and  $37.34\pm10.16$  dB for the PORP group ( $p=0.814$ ), while the mean postoperative ABG levels were  $24.42\pm11.20$  dB,  $23.25\pm10.09$  dB, and  $22.82\pm13.59$  dB in the respective GIC, incus interposition, and PORP groups (Table 2). The ABG gains were  $13.75\pm11.66$  dB in the GIC group,  $15.71\pm11.55$  dB in the incus interposition, and  $14.52\pm9.98$  dB in the PORP group ( $p=0.803$ ).

The mean ABG gain at each frequency by group were as follows: 17.92 dB at 500 Hz, 13.10 dB at 1,000 Hz, 13.32 dB at 2,000 Hz, and 7.67 dB at 3,000 Hz in the GIC group; 17.85 dB at 500 Hz, 15.82 dB at 1,000 Hz, 16.64 dB at 2,000 Hz and 12.53 dB at 3,000 Hz in the incus interposition group; and 18.73 dB at 500 Hz, 17.21 dB at 1,000 Hz, 12.17 dB at 2,000 Hz, and 9.91 dB at 3,000 Hz in the PORP group. When considering the ABG gains for 500 Hz, 1,000 Hz, 2,000 Hz and 3,000 Hz, no statistically significant difference was found among the groups, which had respective  $p$  values of 0.977, 0.567, 0.377 and 0.363 for the 500, 1,000, 2,000, and 3,000 Hz.

Upon performing the multivariate linear regression, neither surgery type ( $p=0.755$ ) nor preoperative MERI index ( $p=0.614$ ) exhibited any statistically significant effect on postoperative change in ABG levels (Table 3). The mean follow-up period was 35 months in the GIC group, 36 months in the incus interposition group, and 27 months in the PORP group, with a 33-month mean for all patients (Range=12-88 months).

## DISCUSSION

Debates on ossiculoplasty materials are still ongoing in the otological practice, with no optimal material having yet been defined. This study reviewed the ABG gain scores for ossiculoplasty techniques performed with three different materials (i.e., GIC, the incus and titanium PORP) in regard to Austin-Kartush type A defects. All three patient groups had comparable hearing gains.

Serviceable hearing requires normal hearing pathways from the auricula to the central auditory cortex. Patients with chronic otitis media may suffer from tympanic membrane perforation, ossicular erosion or fixation, tympanosclerosis, and infectious events that may result in various degrees of hearing loss. Tympanic membrane perforations and erosion of the incus long process are quite commonly encountered, and many different materials are currently being used to rebuild the integrity of the ossicular chain. The features of these introduced materials should include being bioinert, cost-effective, easy to use, resistant to recurrent infections, low extrusion, and time saving. In addition, optimal methods for ossicular reconstruction are those that

**Table 2: Preoperative and postoperative ABG scores according to ossiculoplasty types**

	GIC (n=28)	II (n=28)	PORP (n=23)	Total (n=79)
<b>Preoperative ABG</b>				
Grade I (0-10 dB)	0	0	0	0
Grade II (11-20 dB)	1	0	0	1 (1.2%)
Grade III (21-30 dB)	4	4	7	15 (18.9%)
Grade IV (>30 dB)	23	24	16	63 (79.7%)
<b>Postoperative ABG</b>				
Grade I (0-10 dB)	2	1	4	7 (8.8%)
Grade II (11-20 dB)	10	14	9	33 (41.8%)
Grade III (21-30 dB)	9	6	5	20 (25.3%)
Grade IV (>30 dB)	7	7	5	19 (24%)

ABG: air-bone gap, GIC: glass ionomer cement, II: incus interposition, PORP: partial ossicular replacement prothesis

**Table 1: Demographic features and the mean middle ear risk index scores of the patients based on ossiculoplasty type**

	GIC (n=28)	II (n=28)	PORP (n=23)	Total (n=79)	p value
Age (year, SD)	35.53±13.93	34.60±14.97	34.0±16.07	34.75±14.76	( $p=0.933$ )
<b>Gender</b>					( $p=0.127$ )
Male	8	11	13	32	
Female	20	17	10	47	
<b>Side</b>					
Right	11	19	10	40	
Left	17	9	13	39	
MERI (SD)	4.57±1.25	4.89±1.47	4.78±1.59	4.74±1.42	( $p=0.699$ )

GIC: glass ionomer cement, II: incus interposition, PORP: partial ossicular replacement prothesis, MERI: middle ear risk index

**Table 3: Multivariate linear regression of c-ABG**

Model	Unstandardized Coefficients		Standardized Coefficients	t	p	95.0% Confidence Interval for $\beta$	
	$\beta$	Standard Error	$\beta$			Lower Bound	Upper Bound
Constant	15.851	5.194		3.052	0.003	5.505	26.196
Surgery type	.492	1.572	.036	.313	.755	-2.640	3.624
MERI index	-.449	.888	-.058	-.506	.614	-2.218	1.319

Dependent variable: c-ABG: change-air-bone gap

best mimic the ossicular chain anatomically and physiologically. Prostheses are used for implementing any function in the human body and they consist of the artificially developed materials. Therefore, POPRs replace the incus in order to restore hearing. Ossicular reconstruction can also be performed with tissue grafts (called autografts, homografts, and allografts). Autografts involve grafts of the cartilage (tragal or conchal), cortical bone, or ossicle (the incus remnant or malleus head), and these autografts have biocompatible properties, no additional cost, low extrusion rates, and low likelihood of contagious disease transmission. The drawbacks of autografts are graft migration or resorption as a result of recurrent infections, as well as the autograft incus possibly containing microscopic cholesteatoma (6). Allografts that are fabricated as an ossicular reconstruction prosthesis are biocompatible and they have an additional cost. They are ready to use, but adjusting the length, tension, and position of the prosthesis requires experience. Another subject to consider is prosthesis extrusion that can be avoided by placing a small piece of cartilage between the prosthesis and the tympanic membrane (7).

Glass ionomer cement has powder and liquid components. When these two components are mixed in an *in vitro* medium, an exothermic reaction happens. The mixture hardens within a few minutes and can be used easily once it becomes semisolid. It should not be used before becoming semisolid, because thermal injury may occur as a result. In addition, the liquid phase may be less viscous and end up damaging the surrounding structures. In neurotological practice, GIC has been demonstrated to lead to aluminum encephalopathy and irreversible neuronal blockage (8). Therefore, attention should be paid to the presence of labyrinthine fistula, perilymphatic fistula, or gusher and dehiscence in the fallopian canal when using GIC. Using GIC may provide a more anatomical reconstruction compared to other methods and GIC is MRI compatible material as well. GIC use, with low cost, has also been demonstrated to enable rather successful hearing results when used to repair defects in the incus long process (3, 5, 9). ABG gains are higher when using GIC (17.0±11.96 dB) compared to incus interposition (11.0±13.02 dB) (5). Conversely, some studies have reported similar postoperative hearing gains to have been obtained in patients regardless of whether GIC or incus interposition has been used for the ossiculoplasty (3, 10). With regard to defects in the incus long process, Dere et al. (10) reported that ABG declined from 27 dB preoperatively to 20.7 dB postoperatively when using GIC. Successful ABG closure rates (i.e., 10 dB or greater gain in ABG) occurred in 78.6% of GIC patients and 43.0% of incus interposition patients

(5). Postoperative ABG was 20 dB or less in 42.8% of the GIC patients in the current study.

Incus interposition may be one of the options among ossicular reconstruction techniques, but the incus can occasionally be completely absent or useless. A malleus and incus surrounded by cholesteatoma may exhibit histologically microscopic cholesteatoma on their surfaces (31.6%) and no intra-ossicular cholesteatoma, which may render the incus remnant unreliable for ossicular reconstruction (11). Additionally, examining the incus with an operating microscope with regard to cholesteatoma is unreliable (12). An acetabulum correspondence to the stapes capitulum and a groove correspondence to the malleus handle can be formed so that the reshaped incus becomes more stable. While shaping the incus, however, care should be taken to avoid thermally damaging it. For additional stabilization, the incus may furthermore be attached to the malleus handle and stapes capitulum with a small amount of GIC. Additionally, short- and long-term postoperative ABG results in patients with the incus interposition are comparable (13). Magnetic resonance imaging also does not constitute any problem in patients who ossicular reconstruction has been performed with the incus remnant.

O'Reilly et al. suggested a postoperative ABG of 20 dB or less in 66.4% of patients who'd undergone an incus interposition, with a MERI score of 3.78±1.79 (6). At the 12<sup>th</sup> postoperative month, 53.5% of the current study's patients had an ABG of 20 dB or less in the incus interposition group.

Partial ossicular replacement prostheses are fabricated from diverse materials containing titanium, hydroxyapatite, and Plastipore. Extrusion constitutes an important problem for an ossicular prosthesis in direct contact with the tympanic membrane. A small piece of cartilage placed on the headplate of the titanium PORP can be enough to prevent extrusion. PORPs with adjustable length also allow one to adjust a proper-prosthesis length for the distance between the stapes capitulum and tympanic membrane (14). The weight of the prosthesis can impair sound transmission, with heavier prostheses having lower sensitivities for higher frequencies in this regard. Moreover, higher tensions in prosthesis placement may cause resonance frequency shifts toward higher frequencies (15). Titanium in the middle ear of rabbits has been histologically indicated to be coated by normal middle ear mucosa without signs of inflammation (e.g., no accumulation of macrophage or giant cells) (16). Martin and Harner [17] demonstrated an ABG ≤ 20dB to be seen in 68% of patients who've used a PORP, and

ossiculoplasty with bone cement and PORP in incus defects has been shown to provide similar hearing gains regarding ABG (18). Postoperative ABG in the current study was 20 dB or less in 56.5% of the patients in the PORP group.

## CONCLUSION

Defects in the incus long process or the lack of the incus due to COM may be repaired with GIC, incus interposition, or titanium PORP, with each showing similar ABG gains. Small defects of the incus long process (smaller than one-third of the incus long process) may be amenable to ossiculoplasty with GIC, while ossiculoplasty may be performed using incus interposition or titanium PORP for large defects exceeding two-thirds the length of the incus long process).

**Ethics Committee Approval:** This study was approved by Mersin University Clinical Research Ethics Committee (Date: 11.05.2022, No: 2022/313).

**Informed Consent:** Written informed consent was obtained.

**Peer Review:** Externally peer-reviewed.

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